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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,089	09/24/2001	Shahzi Iqbal		7293

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EXAMINER
SPIEGLER, ALEXANDER H

ART UNIT	PAPER NUMBER
1637	14

DATE MAILED: 08/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/961,089	CHIN ET AL.	
	Examiner	Art Unit	
	Alexander H. Spiegler	1637	

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachm nt(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

1. This action is in response to Paper No. 8, filed on March 4, 2003. Currently, claims 26-47 are pending. Any objections and rejections not reiterated below are hereby withdrawn. Specifically, the 112, 2nd paragraph, 102 and 103 rejections have been withdrawn in view of Applicants cancellation of Claims 1-25.

2. The rejections contained herein have been necessitated by Applicants amendment (i.e., addition of new claims 26-47). Accordingly, this action is made FINAL.

Specification

3. The claims are objected to because of the following informalities:

A) In Claim 27, Applicants could amend "for the RNA strands" to "**from** the RNA strands".

B) In Claim 28, Applicants could amend "radioactive labeled" to "radioactively labeled".

C) In Claim 39, Applicants could amend "selected from a group comprising" to "selected from the group consisting of".

D) In Claim 40, Applicants could amend "developmental, change" to "developmental change".

E) In Claim 41, Applicants could amend "the cDNA strands and RNA strands with common sequences hybridizing" to "hybridizing the cDNA strands and RNA strands with common sequences".

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 28, 31, 36, 38 and 41-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 28 and 42 over "RT-PCR utilizes radioactive labeled to anchored oligo dT primers" because it is not clear if the dT primers are radioactively labeled or some other aspect of the RT-PCR reaction utilizes radioactive labels.

B) Claims 31 and 36 over "the unhybridized cDNA strands", "the unhybridized cDNAs or RNAs" and "the unhybridized cDNA strands or RNA strands" because these recitations lack antecedent basis, as Claim 26 (from which the claims depend) does not recite "unhybridized cDNA strands or RNA strands" or "unhybridized cDNAs". See MPEP 2173.05(e).

C) Claim 38 over "photographic plate" because it is not clear as what is meant by this recitation, it is not an art recognized term and the specification does not define what is encompassed by this recitation.

D) Claims 41-47 are indefinite because claim 41 is drawn to a method for determining differences between a first sample of cDNA and a second sample of RNA strands, however, the final step is for degrading cDNA/RNA compliments. The claims do not set forth the relationship between degrading cDNA/RNA compliments and determining differences between a first sample of cDNA and a second sample of RNA strands. Therefore, it is unclear as to whether the claims are intended to be limited to a method of determining differences between a first sample of cDNA and a second sample of RNA strands or degrading cDNA/RNA compliments.

Claim Rejections - 35 USC § 112, 1st Paragraph (New Matter)

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 35 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicants have added Claims 35 and 47, which recite the use of "Exonuclease IV". However, "Exonuclease IV" was not previously recited in the specification or claims. Therefore, because there is no support for the recitation of "Exonuclease IV", the addition of Claims 35 and 47 constitutes new matter.

It is noted that support does exist for the use of "Exonuclease VII".

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 26-33 and 36-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Sytkowski et al. (USPN 5,804,382).

Regarding Claims 26 and 41, Sytkowski teaches a method for eliminating redundant sequences comprising:

a) isolating RNA strands from a first sample (see Fig. 1, col. 2, 5-7, and cols. 14-15, for example);

b) isolating RNA strands from a second sample (see Fig. 1, col. 2, 5-7, and cols. 14-15, for example);

c) generating cDNA strands from the RNA strands from the first sample (see Fig. 1, col. 2, 5-7, and cols. 14-15, for example);

d) mixing the cDNA strands of the first sample with the RNA strands from the second sample, the cDNA strands and RNA strands with common sequences hybridizing to form cDNA/RNA compliments (see Fig. 1, col. 2 and 6-7, for example)

e) degrading the compliments (see Fig. 1, col. 2 and 7, for example).

Regarding Claims 27-28 and 42, Sytkowski teaches generating cDNA by RT-PCR using oligo dT primers (col. 14, ln. 50-64, for example).

Regarding Claims 29-30 and 39-40, Sytkowski teaches that either the first or second sample can be a healthy or diseased tissue (see col. 2. ln. 32-43, col. 4, ln. 39-49, for example).

Regarding Claim 31 and 43, Sytkowski teaches amplifying unhybridized (e.g., single-stranded) cDNA strands (see col. 7, ln. 50-62, for example).

Regarding Claims 32-33 and 44-45, Sytkowski teaches the methods can be done with a plurality of samples (i.e., producing a second set of cDNA strands) (see abstract, col. 1, ln. 55-60), and that the method can be repeated (i.e., amplifying a second set of cDNA strands using PCR (see col. 2, ln. 61-65, col. 7, ln. 50-62, for example).

Regarding Claims 36-38, Sytkowski teaches displaying and reading the unhybridized cDNAs or RNAs using electrophoresis and reading the unhybridized cDNA strands or RNA strands with a photographic plate (see cols. 17-18).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 34 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sytkowski et al. (USPN 5,804,382), as applied to claims 26-33 and 36-45 above, and further in view of Zeng et al. (USPN 5,25,471, previously cited).

The teachings of Sytkowski are presented above. Specifically, Sytkowski teaches a method for eliminating redundant sequences comprising the claimed method. Sytkowski does not teach degradation of the compliments using Exonuclease III.

However, Zeng teaches that Exonuclease III can be used for degradation of compliments (see col. 1).

In view of the teachings of Zeng, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to have modified the method of Sytkowski so as to have degraded the compliments of the claimed invention, in order to have achieved the benefit of providing an equally effective means of degradation for use in detecting differentially expressed genes.

Conclusion

13. No claims are allowable.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (703) 308-2199. If attempts to reach Carla Myers are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
August 19, 2003

GARY BENZION, PH.D
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